# iPLEDGE PROGRAM FREQUENTLY ASKED QUESTIONS

- A. TECHNICAL ASSISTANCE
- **B. PATIENT**
- C. ALL USERS

#### A. TECHNICAL

# What are the steps for first-time login to iPLEDGE?

Once registered, you will receive your username and password in the mail. Upon first login to iPLEDGE you will be asked to select a personal 4-digit numeric password and select a date of personal significance. The selection of a personal password is a security feature that ensures password confidentiality. A date of personal significance is collected by the system as confidential data that will be asked of you for identity authentication purposes should you require assistance from a Call Center operator during your participation in the iPLEDGE program. The date of personal significance can be any memorable date such as your birth date or wedding date.

If you are logging into iPLEDGE via phone or web for the first time you will enter your Username and Password from the user form that was mailed to you [Please see "How can I login using my telephone?" or "How can I login using the web?"]. Immediately after you have successfully logged in the system will ask you to select your personal password. You will be asked to enter the old (original) password from your user form and then you will enter a new 4-digit number of your choice. You will use the new password you have just chosen to login again in the future. To continue, you will be asked for your new password, then you will be asked to enter your date of personal significance twice. If you are using the telephone system you will enter the date in a mm/dd/yyyy format. If you are using the iPLEDGE website you will enter the date in a mm/dd/yyyy format using the forward slash key. Upon successful entry of the date of personal significance the system will proceed to your main menu of options and you may begin performing functions in the iPLEDGE system.

## How can I login using the web? How do I handle Internet browser issues?

To use the iPLEDGE web functionalities it is required that you use Internet Explorer 6.0 or greater. If you do not have this Internet browser, you can download it at <a href="www.microsoft.com">www.microsoft.com</a>. To login to iPLEDGE go to <a href="www.microsoft.com">www.microsoft.com</a>. To login to iPLEDGE, the screen. Type your username and password into the appropriate boxes. For example, if your username is ABC123, type exactly ABC123 in the Username box. If your password is 1234, type 1234 in the Password box. Click on the green "Login" button and your homepage with all appropriate functions will appear. If you are experiencing browser issues, your browser (i.e. Mozilla Firefox) may be blocking the iPLEDGE site. You can resolve this by 1) Disabling the pop-up blocker completely every time you need to use the site, or 2) adding www.ipledgeprogram.com into your browser's list of allowed sites. If this does not resolve the issue, it is recommended that you use Internet Explorer 6.0.

#### What should I do if I become locked out of iPLEDGE?

If you make three unsuccessful attempts to login to iPLEDGE, a security feature that locks your account is deployed. Your account will automatically unlock after 30 minutes or you can speak with an iPLEDGE customer service representative to have it unlocked. Call the iPLEDGE Program at 1-866-495-0654 and listen for the option to speak to a representative.

# How can I login using my telephone?

To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system first asks for your iPLEDGE user ID followed by the pound sign. Enter each digit of your user ID/username followed by the \*key on your telephone touchpad. Then press the #key at the end of your username. Refer to the table below.

To Enter	Press	То	Press	To Enter	Press	To Enter	Press
		Enter					
2	2*	A	22*	J	55*	S	77777*
3	3*	В	222*	K	555*	T	88*
4	4*	С	2222*	L	5555*	U	888*
5	5*	D	33*	M	66*	V	8888*
6	6*	Е	333*	N	666*	W	99*
7	7*	F	3333*	О	6666*	X	999*
8	8*	G	44*	P	77*	Y	9999*
9	9*	Н	444*	Q	777*	Z	99999*
0	0*	I	4444*	R	7777*	1	1*

For example, if your username is 12345, type 1\*2\*3\*4\*5\*# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 222\*555\*1\*2\*3\*4\*5\*#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no \* or # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.

# How are iPLEDGE patient numbers assigned?

Once a Prescriber performs the "Activation" step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber's address via UPS. The shipment includes two yellow kits (binders) for female patients of childbearing potential and two green kits (binders) for male patients or female patients who cannot get pregnant. Inside each kit is a tab labeled "Patient Identification Card". In this section you will find a patient ID card attached, which can be peeled off and given to the patient along with the kit. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. For each new patient you must have a new patient educational kit available to assign to the patient.

### How can I order additional program materials?

To order additional program materials prescribers must first login to iPLEDGE via telephone or web. If you are accessing the system by telephone you must login and then choose option 4, "To hear options on requesting program information." The system will guide you through the ordering options. If you are accessing the system by web you must login and then click on "Order Materials" from the options listed down the left side of the screen. The system will display the options so you can place your order. The materials you order should be delivered to you within 7 to 10 business days from the order date.

#### Why is the "Confirm Counseling" button not available for my patient on the web?

iPLEDGE enforces the requirements of the program, which include allowing only one prescription per patient per month. If your patient is not eligible for the next monthly visit according to the program timelines, the "Confirm Counseling" activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapses from the previous counseling date, the system will allow you to enter the next counseling date.

#### **B. PATIENTS**

## How do I register with the iPLEDGE program and receive my username and password?

A patient's prescriber must first "register" them with the program. The prescriber will provide the patient with an ID card with a username. After a prescriber registers a patient, the patient will be mailed their password.

# I either lost or forgot my password. How do I reset my password?

If a patient loses their password and they know their date of personal significance and their preferred method of communication is email, they can reset their password on the web system and it will be emailed to them. If this does not work, they can call iPLEDGE at 1-866-495-0654 for a password reset and this password will be provided over the phone upon authentication.

### How do I find an iPLEDGE participating pharmacy?

Patients should login to <u>www.ipledgeprogram.com</u> and consult with online pharmacy finder to make sure a pharmacy is participating in iPLEDGE.

#### C. ALL USERS

# If a patient's 7-day prescription authorization window expires before they arrive at the pharmacy to fill the prescription, is there any way to override the system?

No. A lapse in treatment would result when a registered patient does not pick up the isotretinoin prescription within seven days <u>after</u> the office visit, the office visit being day 1. This may result in a patient missing isotretinoin treatment for no less than 23 days. Patients should make every effort possible to complete the iPLEDGE program requirements and pick up the prescription within the 7-day window to avoid a lapse in isotretinoin treatment.

# Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?

At this time, there is no test database. Please refrain from entering dummy data in the iPLEDGE system as that could negatively impact patient data that is reported to the FDA.

#### **How can I download iPLEDGE materials?**

Users can download the iPLEDGE materials from the website using version Acrobat 7.0. The link to this free Acrobat download is available on any page that has materials available for download.

# Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?

Residency is not a requirement of the program as long as patients see a doctor in the U.S. and fill their prescription in the U.S. However, a U.S. mailing address must be provided.

#### Will the manufacturers reinstate veterinary use of isotretinoin?

Isotretinoin is for human consumption only. At this time, there are no plans to include animals in the iPLEDGE program.

#### Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?

Hospital pharmacies must follow all the requirements of the iPLEDGE program and cannot process partial isotretinoin prescriptions (or break blister packs). All pharmacies need to dispense a 30-day supply of isotretinoin because the iPLEDGE system will allow one prescription authorization a month.